IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.	:	10/478,262 Confirmation No. 2549
Applicants	:	Evert J. BUNSCHOTEN et al.
Filed	:	May 25, 2004
Title	: :	PHARMACEUTICAL COMPOSTION FOR USE IN HORMON REPLACEMENT THERAPY
Group Art Unit	:	1617
Examiner	:	San Ming R. HUI
Customer No.	:	28289

Application No.	:	10/478,264 Confirmation No. 4962
Applicants	:	Evert J. BUNSCHOTEN et al.
Filed	:	May 25, 2004
Title	: :	USE OF ESTROGEN COMPOUNDS TO INCREASE LIBIDO IN WOMEN
Group Art Unit	:	1617
Examiner	:	San Ming R. HUI
Customer No.	:	28289

Application No.	:	10/478,357 Confirmation No. 3771
Applicants	:	Evert J. BUNSCHOTEN et al.
Filed	:	May 25, 2004
Title	: : :	DRUG DELIVERY SYSTEM COMPRISING A A TETRAHYDROXYLATED ESTROGEN FOR USE IN HORMONAL CONTRACEPTION
Group Art Unit	:	1617
Examiner	:	San Ming R. HUI
Customer No.	:	28289

Application No.	:	10/517,509 Confirmation No. 1291
Applicants	:	Herman J. T. Coelingh Bennink et al.
Filed	:	June 13, 2005
Title	:	METHOD OF TREATING HUMAN SKIN AND A SKIN CARE COMPOSITION FOR USE IN SUCH METHOD
Group Art Unit	:	1617
Examiner	:	Samira JEAN-LOUIS
Customer No.	:	28289

DECLARATION

I, Strauss III, Jerome F. declare and state the following:

1. A detailed listing of my publications, together with details of my education, are given in my *curriculum vitae* which is attached as Exhibit A.

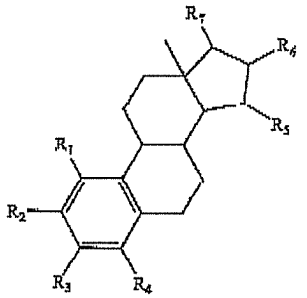
2. Based on my academic training and professional experience, I consider myself an expert in the field of estrogen-related therapies and treatments, and I was such a person in 2001 and 2002.

3. I have received copies of patent applications that I understand were filed in the United States and correspond to the above-captioned applications.

4. I understand that the above mentioned patent applications relate to:

- new methods of contraception (Appln. 10/478,357);
- new methods of hormone replacement therapy (Appln. No. 10/478,262);
- a new method of increasing female libido (Appln. No. 10/478,264);
- a new method treating vaginal dryness (Appln. No. 10/517,509).

The aforementioned methods have in common that they comprise administration of the following estrogenic component:



wherein R_1, R_2, R_3 and R_4 independently are a hydrogen atom, a hydroxyl group or an alkoxy group with 1-5 carbon atoms. R_5, R_6 and R_7 are hydroxyl groups. No more than three of R_1, R_2, R_3 and R_4 are hydrogen atoms. The invention also includes using variations of this formula, such as precursors capable of liberating a substance according to the aforementioned formula and mixtures of one or more of the aforementioned substances and/or precursors. One embodiment of the aforementioned formula is estetrol.

5. I have also received copies of Office Actions that have been issued in relation to the above referenced pending patent applications. Specifically, I have received copies of the following Office Actions:

OA-1 - 10/478,262 (Non-final Office Action mailed on May 15, 2008)
OA-2 - 10/478,264 (Non-final Office Action mailed on March 6, 2008)
OA-3 - 10/478,357 (Non-final Office Action mailed on May 16, 2008)
OA-4 - 10/517,509 (Non-final Office Action mailed on March 26, 2008)

6. I have further received copies of the following references that I have been told have been cited in the above mentioned Office Actions against the independent claims of the above referenced pending patent applications.

Publications mentioning estetrol:

D1 US 5,211,952 (Spicer et al.) – cited in OA-4

D2 US 5,340,584 (Spicer et al.) – cited in OA-2

D3 US 5,340,586 (Pike et al.) – cited in OA-1, OA-2 and OA-3

D4 US 2004/0192598 (Kragie) – cited in OA-4

D5 Holinka, Biology of Reproduction, 1979; 20(2): 242-246 [1] – cited in OA-1 and OA-2

D6 Holinka, Biology of Reproduction, 1980; 20(4): 913-926 [2] – cited in OA-1 and OA-2

Publications not mentioning estetrol:

E1 Ullom –Minnich, American Family Physician, 1999; 60: 194-202 – cited in OA-1

E2 Katzung, Basic and Clinical Pharmacology, 6th ed., 1995, 608-624 – cited in OA-3

E3 Willhite et al. (Pharmacotherapy, 2001, vol. 21, issue 4, 464-480 – cited in OA-4

E4 Sitruk-Ware et al. (Schweiz. Rundsch., Med. Praxis, 1997, vol. 86, No. 33, 1245-1248 – cited in OA-4

It is my understanding that the independent claims of the pending patent applications that are the subject of this Declaration were rejected as being unpatentable over the above cited references under 35 U.S.C. 103(a) (obviousness). I have been asked to comment on my understanding of the state of the art prior to June 11, 2002, which I understand is the priority date for Appln. No. 10/517,509. Particularly, I have been asked whether, prior to June 11, 2002, a person of ordinary skill in the art would have considered it obvious to use estetrol in the pharmacological applications listed in § 4. More particularly, I have been asked whether, prior to the June 11, 2002, a person of ordinary skill in the art would have been motivated to use estetrol in the pharmacological applications listed in § 4, and whether the discovery that estetrol was pharmacologically useful in these applications is unexpected and surprising.

7. It is my view that, prior to June 11, 2002, for the reasons presented below, a person of ordinary skill in the art would not have expected estetrol to be pharmacologically useable, and that the Applicants were the first to discover the pharmacological usefulness of estetrol. In addition, and more particularly, it is my opinion that, prior to June 11, 2002, a person

of ordinary skill in the art would not have expected estetrol to be pharmacologically active when orally administered.

8. I declare that before June 11, 2002 I had no knowledge of any concrete pharmacological application of estetrol. Furthermore, before June 11, 2002, I did not expect that estetrol can be used effectively as a drug in therapeutic treatments or in hormonal contraceptives. Based on the data from scientific literature that was available before June 11, 2002, I would have expected estrogenic activity of estetrol to be too low for pharmacological applications, such as the ones recited in Applicants' claims.

9. My view that a person of ordinary skill in the art would not have expected estetrol to be pharmacologically active is supported by leading textbooks in the field of endocrinology. In "Clinical Gynecologic Endocrinology and Infertility" [3] estetrol is solely mentioned in Chapter 8 (The Endocrinology of Pregnancy) under the subheading "Measurement of Estrogen in Pregnancy" (page 287) and in the index. On page 287 it is stated that "Estetrol (15alpha-hydroxyestriol) is formed from a fetal precursor and is very dependent on 15alpha-hydroxylation activity in the fetal liver. The capacity for 15alpha-hydroxylation of estrogens increases during fetal life, reaching maximum at term. This activity then declines during infancy and is low, absent or undetectable in adults. There is no clinical use for maternal blood or urine estetrol measurements during pregnancy. The clinical use of maternal blood and urine estetrol measurements is of no advantage over the usual estriol assessment."

10. The unexpected pharmacological activity of estetrol is associated with Applicants' discovery that estetrol has a surprisingly long *in vivo* elimination half-life. Applicants' finding that estetrol has a terminal elimination half-life of about 28 hours, which is very much longer than that of the other pregnancy hormone estriol (5-10 minutes), was very unexpected and provided the clue towards its pharmacological usefulness as will be further explained below.

11. It is my understanding that the claims of the pending patent applications that are the subject of this Declaration were rejected as obvious because it has been asserted by USPTO examiners that it is known from the references cited in § 6:

(i) to use estrogens with or without progestins in HRT (reference E1);

(ii) to use a combination of estrogen and progestin in hormonal contraceptives (reference E2);

(iii) to use estrogen to treat decreased libido in women taking GnRH agonists (reference D2); and to use a combination of estrogen and androgen to treat decreased libido in oophorectomized women (reference D3);

(iv) to treat vaginal dryness by administering estrogen (references D1, D4, E3, E4).

12. Assuming that the references cited by the USPTO examiners disclose the information contained in § 11 (i) to (iv), I do not think that, in view of these references, it would have been obvious to use estetrol in pharmacological applications described in § 4. I appreciate that the cited references D1 to D4 contain references to estetrol within a lengthy list of other estrogens. Furthermore, I have read the cited papers published by Holinka et al ("Holinka articles")[1,2], which report that parenterally administered estetrol produced estrogenic changes in the immature rat uterus.

13. I declare that although the cited references D1 to D4 list estetrol among candidate estrogens for pharmaceutical use, it is my view that a person of ordinary skill in the art having knowledge of the aforementioned patent publications D1 to D4 and the "Holinka articles", would not have expected estetrol to be pharmacologically useable for the reasons presented below.

14. The mere mentioning of estetrol in a long list of candidate estrogens in D1 to D4 without any experimental data to support the viability of pharmaceutical uses described in these patents, in my view would not have provided a person of ordinary skill in the art with any motivation to actually employ estetrol in these pharmaceutical uses. Furthermore, the aforementioned US patent publications would not have provided a person of ordinary skill in the art with any motivation to replace the estrogens employed in the uses (i) to (iv) mentioned in §11 with estetrol.

15. In Holinka (1979)[1] the estrogenic activity of estetrol was evaluated by examination of uterine responses to subcutaneous administration of estetrol in doses of 10 and 50 µg/100g body mass. The effects were compared to those obtained by administration of 1 µg/100g body mass estradiol or estriol. The last paragraph of the abstract of Holinka (1979) reads as follows "It is concluded that estetrol administered as a single dose or in 2 doses at a 24 h interval

is a weak estrogen which produces effects of short duration. It cannot, however, be considered entirely devoid of estrogenic activity, even though true uterine hyperplasia, as estimated by DNA content, was not promoted by administration of the two 50 µg/100 g bw doses of estetrol".

16. Holinka (1980)[2] describes the results of a study that aimed to extend the study described in Holinka (1979). In this follow-up study estrogenic effects on immature rat uterus of estetrol and the antiestrogen tamoxifen were compared with those of estradiol and estriol. This time, estetrol was injected subcutaneously for 3 days at a dose of 50 µg/100g body mass, a dose 50 times greater than the dosages of estradiol and estriol that were administered subcutaneously (at a dose of 1 µg/100g body mass). The last paragraph of the abstract of Holinka (1980) reads as follows: "In general estradiol treatment promoted the most marked changes, followed by tamoxifen, estriol and estetrol. On the basis of the present biochemical and morphological results, it is concluded that estetrol and tamoxifen have estrogenic effects on the immature rat uterus. However, the estrogenic potency of estetrol, relative to estradiol or estriol was low at the dosage and timing of administration used in these experiments; effects of estetrol introduced in the circulation at a constant rate were not evaluated. These results suggest that the conversion of estradiol to estetrol in the human fetus represent an efficient mechanism of inactivation of the placental hormone." Specifically, even though Holinka et al administered 50 times more estetrol than estradiol or estriol, the observed uterotropic effects of estetrol were still smaller than those of estradiol or estriol. Thus, from Holinka (1980), one of ordinary skill in the art would expect estetrol to be more than 50 times less effective than a weak estrogen, such as estriol.

17. It is my view that a person of ordinary skill in the art would have deduced from the Holinka articles that estetrol has estrogenic activity, but that it is a much weaker estrogen than the already weak estrogen estriol, given that estetrol injected subcutaneous at 50 µg/100g body mass exhibited less estrogenic activity than estriol injected subcutaneous at 1 µg/100g body mass. Estriol is a very weak estrogen due to its low receptor affinity in combination with its very short half-life of 5-10 minutes. Since the Holinka articles teach that estrogenic activity of estetrol is at least 50 times lower than that of a weak estrogen for which very few practical applications exits, the Holinka articles would not have provided a motivation for a person of ordinary skill in the art to investigate the potential pharmacological usefulness of estetrol.

18. Applicants have demonstrated that, contrary to what a person of ordinary skill in the art would have expected, estetrol is pharmacologically very active. The unexpected pharmacological activity of estetrol is associated with its surprisingly long *in vivo* elimination half-life. Whereas, under comparable conditions, the human estrogens estradiol and estriol have terminal elimination half-lifes of about 30 minutes and 5-10 minutes respectively, estetrol has a terminal elimination half-life of about 28 hours. A person of ordinary skill in the art would have expected estetrol to be more comparable to estriol than estradiol given that (i) estetrol differs from estriol by only 1 hydroxy group and from estradiol by 2 hydroxy groups and (ii) both estriol and estetrol are produced during pregnancy. Hence, Applicants' finding that estetrol has a terminal elimination half-life that is 168-336 higher than that of the other pregnancy hormone estriol, was very unexpected and provided the clue towards its pharmacological usefulness. Based on my knowledge of the relevant art, I conclude that Applicants are the first to have discovered estetrol's pharmacological usefulness. As explained herein before, it is my view that, prior to June 11, 2002, a person of ordinary skill in the art would not have anticipated this usefulness.

19. In addition, I conclude that Applicants are the first to have discovered estetrol's high oral bioavailability. This finding is truly surprising as other human estrogens, notably estradiol, estriol and estrone, exhibit low oral bioavailability because they are largely metabolized into inactive metabolites during the so called "first pass" through the liver after oral administration. It is my opinion that, given that estetrol's estrogen receptor affinity was known to be considerably lower than that of estradiol and estriol, a person of ordinary skill in the art, being aware that known human estrogens are largely metabolized during the first pass, could not have anticipated the high oral bioavailability of estetrol. Thus, in my view, prior to June 11, 2002, a person of ordinary skill in the art could not have anticipated estetrol's oral pharmacological activity.

20. As mentioned herein before, it is my view that a person of ordinary skill in the art could not have anticipated the advantageous pharmacological properties of estetrol that Applicants have described in the above referenced pending patent applications and that have been reported in scientific articles that were published after June 11, 2002. In particular, such a skilled person could not have foreseen the favorable pharmacokinetic (ADME) and

pharmacodynamic properties of estetrol. These favorable properties of estetrol are remarkable since they are much less manifest in other human estrogens, notably estradiol, estriol and estrone. The unexpected favorable properties of estetrol that have been described by Applicants in the aforementioned pending patent applications and that were not known before June 11, 2003 include:

A. Long *in vivo* elimination half-life in the human

- In the first human study with estetrol, a dose-independent terminal elimination half-life of about 28 hours after single oral administration to early postmenopausal women was demonstrated [4,5]. Terminal elimination half-lifes of the human estrogens estradiol and estriol under comparable conditions are about 30 minutes and 5-10 minutes respectively [3].

B. No binding affinity for sex hormone binding globulin (SHBG)

- Competitive ligand binding assays did not detect any binding of estetrol to the SHBG steroid-binding sites [4,6]. By contrast, estradiol is bound by SHBG with high affinity [6].

C. No ERα-mediated increase in SHBG production by HepG2 or Hep89 cells

- Fluorometric assays in wild-type human HepG2 and Hep89 cells showed that estetrol does not stimulate ERα-mediated increases in SHBG production by these cells, in contrast to estradiol and estriol [4,6].

D. No conversion to other active metabolites

- Estetrol is an end-stage product of estrogen metabolism [4,5,7]. In contrast, especially after oral administration, estradiol is rapidly and reversibly converted by the liver to the estrogenic metabolites estrone and estrone sulfate.

E. No significant inhibition of P450 enzymes

- At a concentration of 10 µmol/l estetrol has no inhibitory effect on any recombinant human P450 enzymes CYP1A2, CYP2C9, CYP2C19, CYP2D6 and CYP3A4. In contrast, at the same concentration estradiol moderately inhibits CYP1A2 and strongly inhibited CYP2C19 [4,7].

F. Highly selective binding to estrogen receptors ERα and ERβ

- Estetrol tested at a prime concentration of 10 µmol/l, did not show significant (>20%) inhibition of the binding of the respective ligands in 123 of the 124 assays studied (Estetrol only inhibited binding of prazosin at the adrenergic α_{1B} receptor by 23%) [4,7].

G. Estrogen agonist in bone, vagina, myometrium, endometrium and brain, but estrogen antagonist in breast tumor tissue in the presence of estradiol

- Estetrol significantly and dose-dependently inhibited the OVX-related increase in osteocalcin levels, increased bone mineral density and content, and increased bone strength [4,8].
- Estetrol is effective in preventing temperature rises dose-dependently in an animal model considered representative for menopausal vasomotor symptoms [4,9].

  In the modified Allen-Doisy test estetrol was found to have dose-dependent estrogenic effects on the vagina and on the uterus of ovariectomized rats including the endometrium [4,10].
- Estetrol at a twice-daily dose of 0.3 mg/kg and above effectively inhibited ovulation in regularly cycling female rats [4,11].
- Estetrol dose-dependently prevents the growth of chemically induced (DMBA) mammary tumors in rats and has the potential to reduce the number and size of pre-existing mammary tumors [4,12]. By contrast it is well-established that estradiol has proliferative effects on breast tumor cells and tissue.

H. Oral absorption in the human with a strong dose-response relationship suggesting high oral bioavailability

- In a first-in-human study four single doses of 0.1, 1, 10 and 100 mg estetrol were administered orally to early postmenopausal women. High oral bioavailability, a strong dose-response relationship and a long elimination half life (see A) were found. For the first time (oral) pharmacodynamic effects of estetrol were observed since the data showed a strong suppression of follicle stimulating hormone (FSH) with the 100 mg dose and a dose-dependent inhibition of luteinizing hormone (LH) levels [4,5].

The above mentioned features A to D imply that the estrogenic activity of estetrol is much more pronounced than could have been anticipated on the basis of the estrogen receptor affinity studies described in scientific literature before June 11, 2002. Features E and F indicate that it is unlikely

that estetrol administration will induce undesirable side-effects. Feature G indicates that estetrol may suitably be used as a drug in estrogen or hormone replacement therapy (ERT/HRT) including the prevention of osteoporosis (US 10/478,262), the treatment of female sexual dysfunction (US 10/478,264), topical treatment of vaginal atrophy (US 10/517,509) and as the estrogenic component in contraceptives (US 10/478,357). Feature H indicates that estetrol has potential as a once-a-day oral drug for human use.

21. I have not been compensated for the execution of this declaration, or any time I spent relating to this declaration.

22. I declare further that all statements made herein are true to my knowledge; and that these statements were made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under Section 1001 of title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Strauss III, Jerome F. Date 8/26/08

References

1 Holinka et al., *In vivo effects of estetrol on the immature rat uterus.* Biol Reprod 20 (1979) 242-6.

2 Holinka et al., *Comparison of effects of estetrol and tamoxifen with those of estriol and estradiol on the immature rat uterus.* Biol Reprod 22 (1980) 913-26.

3 Leon Speroff, Robert H. Glass and Nathan G. Kase. *Clinical Gynecologic Endocrinology and Infertility.* Baltimore, Maryland, USA. Lippincott Williams & Wilkins, 1999.

4 Coelingh Bennink et al., *Estetrol Review: profile and potential clinical applications,* Climacteric 2008; 11 (Suppl 1): 47-58

5 Visser et al., *First human exposure to exogenous single-dose oral estetrol in early postmenopausal women,* Climacteric 2008; 11 (Suppl 1): 31-40

6 Hammond et al., *Estetrol does not bind sex hormone binding globulin or increase its production by human HepG2 cells,* Climacteric 2008; 11 (Suppl 1): 41-46

7 Visser et al., *In vitro effects of estetrol on receptor binding, drug targets and human liver cell metabolism,* Climacteric 2008; 11 (Suppl 1): 64-68

8 Coelingh Bennink et al., *Oral bioavailability and bone-sparing effects of estetrol in an osteoporosis model,* Climacteric 2008; 11 (Suppl 1): 2-14

9 Holinka et al., *Preventive effect of oral estetrol in a menopausal hot flush model,* Climacteric 2008; 11 (Suppl 1): 15-21

10 Heegaard et al., *Estrogenic uterovaginal effects of oral estetrol in the modified Allen-Doisy test,* Climacteric 2008; 11 (Suppl 1): 22-28

11 Coelingh Bennink et al., *Ovulation inhibition by estetrol in an in vivo model,* Contraception 2008; 77: 186-190

12 Coelingh Bennink et al., *Estetrol, a pregnancy specific human steroid, prevents and suppresses mammary tumor growth in a rat model,* Climacteric 2008; 11 (Suppl 1): 29

EXHIBIT "A"

VIRGINIA COMMONWEALTH UNIVERSITY- SCHOOL OF MEDICINE

CURRICULUM VITAE

JEROME F. STRAUSS, III

Home Address: 2805 Monument Avenue, Unit 3
Richmond, VA 23221

Office Address: Sanger Hall, Room 1-01
1101 East Marshall Street
Richmond, VA 23298-0565

Date of Birth: May 2, 1947
Place of Birth: Chicago, IL
Marital Status: Married 1970 - Catherine
Children: Jordan Lawrence, 1978
Elizabeth Johanna, 1981

Education:

1965-69	B.A.	Brown University
1969-74	M.D.	University of Pennsylvania
1970-75	Ph.D.(Molecular Biology)	University of Pennsylvania

Postgraduate Medical Training:

1975-76	Obstetrics and Gynecology Hospital of the University of Pennsylvania

Faculty Appointments:

1976-77	*Associate*, Department of Obstetrics and Gynecology, University of Pennsylvania School of Medicine
1977-82	*Assistant Professor,* Department of Obstetrics and Gynecology, Pathology and Laboratory Medicine and Physiology, University of Pennsylvania
1982-85	*Associate Professor*, Department of Obstetrics and Gynecology, Pathology and Laboratory Medicine and Physiology, University of Pennsylvania
1985-	*Professor*, Department of Obstetrics and Gynecology, Pathology and Laboratory Medicine and Physiology, University of Pennsylvania
1987-	*Associate Chairman*, Department of Obstetrics and Gynecology, University of Pennsylvania
1992-2005	*Luigi Mastroianni, Jr. Professor and founding Director,* Center for Research on Reproduction and Women's Health

University of Pennsylvania

2005- *Dean, School of Medicine* and *Executive Vice President for Medical Affairs*, and *Professor of Obstetrics and Gynecology*, Virginia Commonwealth University

Hospital and Administrative Appointments (University of Pennsylvania):

1978-82 Medical Scientist Training Program Advisory Committee
1980-84 Clinical Research Center Advisory Committee
1981-87 Director, Endocrine Laboratory, Hospital of the University of Pennsylvania
1981-87 Principal Investigator, Institutional alpha fetoprotein screening program for neural tube defects
1982- Member, Cancer Center
1983-90 Member, Long Range Planning Committee Subcommittee on Medical Education
1984- Director, Division of Reproductive Biology Department of Obstetrics and Gynecology
1984- Consultant, PMS Clinic, Department of Obstetrics and Gynecology
1984-89 Consultant, Women's Wellness Center
1985-86 Director, RIA Core Facility, Diabetes and Endocrinology Research Center
1985-86 Committee on AIDS
1985-86 Ad Hoc Committee on Animal Care Facilities
1985-89 Clinical Research Building Design Committee
1985-1993 Executive Committee, Graduate Group on Pathology
1986- Diabetes Research Center Executive Committee
1986-1993 Director, Combined Degree Programs and Medical Scientist Training Program
1986-1993 Advisory Council, Biomedical Graduate Studies
1986-1993 Advisory Council, Medical Scholars Program
1987-1990 Member, Long Range Planning Committee
1987-1991 Member, Curriculum Committee School of Medicine
1987-1989 Member, Search Committee for the Chair of Physiology
1987-1989 Member, Search Committee for the Dean of the School of Medicine
1990 Acting Director, Biomedical Graduate Studies
1990-1993 Associate Dean for Combined Degree Studies and Special Research
1993- Clinical Research Center Advisory Committee
1993-1995 Member, Committee on Appointments and Promotions, University of Pennsylvania Medical Center
1993 Executive Committee, Task Force on Women's Health Services
1995 Search Committee, Chair of Microbiology
1995 Task Force on human pre-embryo research
1996 Committee to review University policy on nepotism
1996-20022 Director, Center of Excellence in Women's Health
1996- Penn-Hughes Scholars in Developmental Biology Advisor Committee
1996- Director, National Cooperative Program in Infertility

Research, University of Pennsylvania
1997 Search Committee, Chair, Department of Medicine
1998 Dean's Committee on the Life Sciences
1999- International Programs Advisory Committee
1999 Committee to Review the Institute for Human Gene Therapy
1999-2002 Academic Review Committee, School of Medicine
1999 Chair, Committee to Review the Department of Genetics
2001 Human Subjects Research Committee
2001 Chair, Committee on Principles of Research Space Utilization

Hospital and Administrative Appointments (Virginia Commonwealth University)

2005- Committee Member, Ex Officio, VCU Health System Authority

Licensure: Pennsylvania, MD018395E

Hospital Staff Appointments

1981-2003 Hospital of the University of Pennsylvania

Graduate Group Appointments at the University of Pennsylvania:

1978-2005 Physiology
1982-2005 Molecular Biology
1985-1996 Pathology (Executive Committee 1985-1992)
1988-2005 Cell and Molecular Biology

Awards, Honors and Membership in Honorary Societies:

1969 B.A. awarded cum laude with Honors in Biology
1969 New York City Health Sciences Training Program Fellowship
1971 Alpha Omega Alpha
1971-75 Medical Scientist Training Program Fellowship
1975 Rittenhouse Award, University of Pennsylvania School of Medicine
1979- John Morgan Society, University of Pennsylvania
1983 Berwick Award for Distinguished Teaching
1983 Medical Student Government Distinguished Teaching Award
1990 Co-author Prize Paper, Society of Reproductive Endocrinologists, American Fertility Society
1990 President's Achievement Award, Society for Gynecologic Investigation
1992 Research Award, Society for the Study of Reproduction
1994 Institute of Medicine, National Academy of Sciences
1994 Transatlantic Medal, British Endocrine Society
2001 Beacon Award, Marine Biological Laboratories
2001 Society for Maternal-Fetal Medicine 2001 Award for Research Excellence (co-author best scientific paper)
2002 Fellow, International Academy of Human Reproduction
2004 Pioneer Award, Frontiers in Reproduction, Marine Biological Lab. And NICHD
2005 Distinguished Graduate Award, University of Pennsylvania School of Medicine
2006 Distinguished Scientist Award, Society for Gynecologic Investigation

2007 Distinguished National Research Service Award, Marine Biological Laboratories and NICHDF

Named Lectureships

1985 James H. Leathem Memorial Lecturer, New Jersey College of Medicine and Rutgers University
1989 Ernest W. Page Memorial Lecturer, University of
1993 Thomas G. Muldoon Memorial Lecturer, Medical College of Georgia
1994 Van Campenhout Memorial Lecturer, Canadian Fertility and Andrology Society
1994 Maternal and Child Health Lecturer, Society for Perinatal Research
1994 First Anita Payne Lecturer, University of Michigan
1995 Serono Lecture, American Society for Reproductive Medicine
1997 Earl R. Plunkett/Wyeth-Ayerst Lecture, University of Western Ontario
1997 John Patrick Memorial Public Lecture, University of Western Ontario
1998 Johns Hopkins-University of Maryland Lecture
1998 Transatlantic Lecture, British Endocrine Societies
1999 Dr. Jacob Probstein Visiting Professor, Washington University
1999 A.V. Nalbandov Memorial Lecture, University of Illinois
1999 The First Jordan M. Phillips Lecturer, American Association of Gynecologic Laparoscopists
2003 Shirley Dungan Kheel Memorial Lecture, Eastern Virginia School of Medicine
2003 Sydney A. Asdell Memorial Lecturer, Cornell University
2005 Cosgrove Memorial Lecture, American College of Obstetricians and Gynecologists
2006 Sidney Guzick Scholar Day Lecturer, University of Rochester
2006 Sheldon Norsley III Memoral Lecture, Richmond Academy of Medicine
2006 Ware-Dunn Lecture, Ware-Dunn Society
2006 Van Campenhout Memorial Lecture, Canadian Fertility Society
2007 Chuengkong Scholar, Chinese Ministry of education

Memberships in Professional and Scientific Societies:

National Societies:
- Endocrine Society
  - Program Committee 1992-1994; Recent Progress in Hormone Research Steering Committee, 1995-1998
- American Physiological Society
- American Association of Pathologists
- Society for Gynecologic Investigation
  - Program Committee 1990, 1991
  - President nominee, 2001
  - President Elect, 2002
  - President, 2003

Society for the Study of Reproduction
Nominating Committee, 1977;
Membership Committee, 1982;
Long Range Planning Committee, 1987;
Director, 1988-1991;
Program Committee, 1991-1993,
Chair, Development and Endowment Committee, 1994 -1997
Blue Ribbon Long Range Planning Committee, 1997
American Fertility Society
Chair, Postgraduate course, 1999
Academy of Clinical Laboratory Physicians and Scientists

Local Societies:
Philadelphia Endocrine Society
Board of Directors, 1978-1981
Philadelphia Lipid Club

Editorial Positions:

1982-1986	Journal of Lipid Research, Associate Editor
1986-1989& 1996-2000	Endocrinology, Editorial Board
1986-1990 & 1999-2003	Biology of Reproduction, Editorial Board
1987-1991	Journal of Lipid Research, Editorial Board
1991-1999	Journal of Steroid Biochemistry and Molecular Biology, Corresponding Editor
1992-	Journal of Women's Health, Editorial Board
1992-	Steroids, Editor
1993-	Journal of the Society for Gynecologic Investigation, Editorial Board
1993-	Journal of Reproduction and Development, Special Advisory Board
1996-1998	Placenta, Editorial Board
1997	Encyclopedia of Reproduction, Associate Editor
1997-2000	Endocrinology, Editorial Board
1999-	Trends in Endocrinology and Metabolism, Editorial Board
1999-	Reference en Gynecologie Obstetrique, Scientific
2000-	Seminars in Reproductive Medicine, Editorial Board
2000-	Journal of Endocrinology, Editorial Board
2000-2005	Human Reproduction Update, Associate Editor
2004-	Science, Board of Reviewing editors
2007-	Molecular Human Reproduction, Associate Editor

Service for the National Institutes of Health and National Science Foundation:

1981	Ad hoc member, Biochemical Endocrinology Study Section, NIH
1983-1987	Member, Biochemical Endocrinology Study Section, NIH
1983	Consultant, National Science Foundation, Regulatory Biology
1983	Special Reviewer, Endocrinology Study Section, NIH
1984	Member, Special Study Section for review of proposals on human infertility
1988	Member, Special Study Section for review of Medical Scientists Training Programs

1988-1992 Member, Population Research Committee, NICHD
1989-1992 Chair: Population Research Committee, NICHD
1991 Co-Chair, Early Development Working Group, Office of Research on Women's Health
1992 Ad Hoc Member, Maternal and Child Health Committee, NICHD
1992 NIEHS Contracts Review Committee
1993- International Cooperative Programs Study Section
1994 NIDA Contract Review Committee
1995 Chair, Conference on establishing an Americas Reproductive Sciences Network
1995- Chair, Reproductive Scientists of the Americas Network
1996 Chair, N.I.C.H.D. Special Study Section for Center grant review
1996- Co-chair Indo-U.S. joint Working Group on Contraception
1997 Special reviewer, HED-1 Study Section
2000 Special reviewer, ENDR-2G1 Study Section
2001 Chair, ENDR-2G1 Study Section
2002 Member, ENDR-2G1 Special Emphasis Panel
2002- National Child Health and Human Development Advisory Council
2003 Chair, Institute of Medicine Committee on Frontiers in Contraception Research

Other service activities:

1983- Consultant, Medical Research Council of Canada, Grant Review
1983- Consultant, Veterans Administration, Division of Research Grants
1983 Review Committee for Middle States Accreditation, Department of Biochemistry and Physiology, Medical College of Pennsylvania
1983-1985 Consultant, Corning Medical, on development of diagnostic reagents
1983 Consultant, Wyeth Pharmaceutical Co., on development of diagnostic reagents
1983 Inspector, College of American Pathologists, Laboratory Standards
1984 Co-organizer, Symposium on Lipoprotein and Cholesterol Metabolism in Steroidogenic Tissues, Quebec, Canada
1984- Consultant, United States-Israel Binational Agricultural Research Development Fund, Grant review
1985-1986 Consultant, Baker Instruments, on development of diagnostic reagents
1986 International Organizing Committee, 1st International Symposium on Ovarian Function, Sapporo, Japan
1987 International Organizing Committee, Workshop on Maternal Recognition of Pregnancy, Jerusalem, Israel

1988-1994 Board of Directors, Ovarian Workshops
1989 Institute of Medicine, National Academy of Sciences
1990 Advisory Group on Assisted Reproductive Technologies
1991 International Organizing Committee, IInd International
1992 Symposium on Ovarian Function, Sapporo, Japan
1990 Co-organizer, Workshop on Uterine and Embryonic factors in Early Pregnancy, Bellagio, Italy

1991 External Consultant, Review of the Department of Ob/Gyn, Yale University

1991-1993 Scientific Advisory Committee VIIIth World Congress on In Vitro Fertilization and Alternate Assisted Reproduction, Kyoto, Japan

1991- Scientific Advisory Committee, Wisconsin Regional Primate Center

1991 Organizing Committee Symposium on Endocrinology of Embryo-endometrial interactions, Bordeaux, France

1991 Institute of Medicine, National Academy of Sciences Committee on Research in Academic Departments of Obstetrics and Gynecology

1991- Reproductive Scientist Training Program, Evaluation and Selection Committees

1992-1995 Ares-Serono Scientific Advisory Board in Reproductive Endocrinology

1993 Scientific Committee, Second International Conference on the Endometrium

1994 Organizing Committee, 3rd International Symposium on Ovarian Function, Sapporo, Japan

1994 Board of Directors, World Congress on Human Reproduction

1994- External Advisory Board, University of Pittsburgh Center for Reproductive Biology

1994-1996 Scientific Advisory Board, Biointerventions Inc.

1994-1997 NIDA Advisory Committee for University of Kansas Contract on Placental Drug Transfer

1995 Consultant, Akzo-Nobel, Organon Pharmaceutical Co.

1996-1999 Chair, Scientific Advisory Board, Reprogen Inc.

1996- Advisory Committee, Burroughs-Wellcome Fund Career Awards (Co-Chair 2000-)

1996- Advisory Board, Perinatology Research Center, Brown University

1997 Organizing Committee, FASEB Conference on fetal vascular physiology

1997-1998 Member, Item-writing Committee, USMLE

1997-2001 Expert Advisory Panel, FIGO

1997- Advisory Committee, University of Maryland Reproductive Sciences Center

1997 Chair, External Advisory Board, Northwestern University Center for Reproductive Sciences

1997- Chair, Scientific Advisory Board, Femme Pharma, Inc.

1998 Scientific Advisory Committee, IVth Sapporo Ovary Symposium

1998-2002 N.V. Organon, Medical Advisory Board

2000-2002 Scientific Advisory Board, GeneFormatics, Inc.

2000 Co-organizer, Society for Gynecologic Investigation Symposium on Biotechnology in the Service of Reproductive Medicine, Salt Lake City, UT

2000-2002 Scientific Advisory Board, DIOGENICS/PLUVITA

2000 Scientific Organizing Committee, Serono Workshop on Reproductive Competence, Santiago, Chile

2000 Scientific Organizing Committee, Serono Symposium on Human Implantation, Madrid, Spain

2000- Chair, External Advisory Board, K-BRIN, State of Kansas Research Consortium

2001 Co-organizer, 2nd International Workshop on Human Human Implantation, Madrid, Spain

2002 Scientific Advisory Committee, Vth Sapporo International Symposium on

	Ovarian Function
2002	Centocor, Clinical Advisory Board on Endometriosis
2002-	Serono, Consultant on clinical applications of recombinant LH
2002-	Board of Directors, Burroughs Wellcome Fund (Executive Committee: 2004-)
2003-	Ortho-McNeil, Consultant
2003	External Review of the Baker Institute, Cornell University
2004-	Scientific Advisory Board, Specialty Laboratories
2004	Review of the Center for Reproduction Research, Columbia University
2004-	Consultant, Serono Foundation
2005-	Berlex Foundation, Board of Trustees
2005	Reviewer, NIEHS Intramural Programs in Reproduction, Board of Scientific Councillors
2006	Ad Hoc Study Section, NIH Director's Awards
2007	Reviewer, Board of Scientific Counselors, NICHD Intramural Programs

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John E. Nestler, M.D.	Professor and Chairman, Department of Endocrinology, Department of Medicine, Medical College of Virginia
Emiliano Soto-Romo, M.D.	Vice-Chairman, Department of Obstetrics and Gynecology, University of Chile
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3. Kraicer, P.F., Strauss, J.F. III: Ovulation block produced by an inhibitor of luteotropin, ergocornine. Acta Endocrinologica **65**: 698, 1970.
4. Strauss, J.F III, Foley B., Stambaugh, R.L.: 20α-hydroxysteroid dehydrogenase activity in the rabbit. Biology of Reproduction **6**: 78, 1972.
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Principal Investigator of Current Grants

R01 HD34612 TDC $785,000	Mechanisms of Fetal Membrane Rupture	9/1/08-12/31/11

R01 HD37416 TDC $1.250,000	Molecular Basis of Human Sperm Motility	4/1/00-3/31/011
March of Dimes TDC $501,000	Genetics of preterm birth	4/1/05-3/31/09
K12HD05581 TDC $2,400,000	VCU Building Interdisciplinary Research Careers in Women's Health	10/1/07-7/30/12
P60MD002256 TDC $4,200,000	National Center on Minority Health & Heath Disparities	10/1/07-7/31/12